

REMARKS

The Examiner rejected claims 25-28 under 35 U.S.C. § 112, second paragraph; claims 1, 4-10, 14, 17-19, and 25-28 under 35 U.S.C. § 102 over U.S. Patent No. 5,733,297 to Forber et al.; claims 11, 13, and 20 under 35 U.S.C. § 103(a) over Forber in light of U.S. Patent No. 6,117,519 to Huebsch et al.; and claims 12, 21, and 22 under 35 U.S.C. § 103(a) over Forber in view of Huebsch in view of U.S. Patent No. 6,355,052 to Neuss et al.

Without prejudice to the pending claims 25-28, Applicants amended to define a first and second axis. Applicants submit that claims 25-28 are now in compliance with 35 U.S.C. § 112, second paragraph.

Applicants submit that claims 1, 4-10, 14, 17-19, and 25-28 are not anticipated by Forber because Forber failed to teach or suggest all of the limitations. In addition, Applicants submit that claims 11, 13, and 20 are non-obvious because Forber and Huebsch, either individually or in combination, failed to make the claimed inventions obvious. Further, Applicants submit that claims 12, 21, and 22 are non-obvious because Forber, Huebsch, and Neuss, either individually or in combination, also failed to make the claimed inventions obvious.

Claim Amendments

Claims 1, 4-14, 17-22, and 25-28 are pending in this application. Applicants amended claims 25-28 to recite, inter alia, a first axis extending from the point on the first loop furthest from the central body to the point on the second loop furthest from the central body and a second axis extending from the point on the third loop furthest from the central body to the point on the fourth loop furthest from the central body. Support for these amendments can be found in the application as originally filed, for example, in FIGS 5A and 5B. None of these amendments introduce new matter.

Claim Rejections – 35 U.S.C. § 112

The Examiner rejected claims 25-28 under 35 U.S.C. § 112, second paragraph, for being indefinite. Specifically, the Examiner alleged that “the first and second loops together” and “the third and fourth loops together” are unclear. Without prejudice to the pending claims, Applicants amended claims 25 and 27 to define the first axis as extending from the point on the first loop furthest from the central body to the point on the second loop furthest from the central body. Similarly, Applicants amended claims 26 and 28 to define the second axis as extending

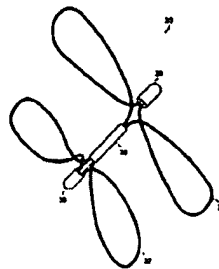
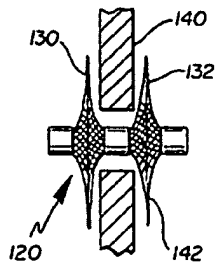
from the point on the third loop furthest from the central body to the point on the fourth loop furthest from the central body.

Applicants respectfully submit that claims 25-28 as amended are now in compliance with 35 U.S.C. § 112, second paragraph. Accordingly, Applicants request that the Examiner reconsider and withdraw the above rejections.

Claim Rejections – 35 U.S.C. § 102(b)

The Examiner rejected claims 1, 4-10, 14, 17-19, and 25-28 under 35 U.S.C. § 102(b) and alleged that they were anticipated by Forber. Applicants respectfully disagree and submit that Forber failed to teach or suggest all of the limitations in the above claims. Specifically, Forber failed to teach or suggest (1) each of the first and second loops defining a first plane substantially parallel to septum primum and septum secundum, (2) each of the third and fourth loops defining a second plane substantially parallel to septum primum and septum secundum, (3) the first and second loops cooperating with the central body to apply a force, perpendicular to the first plane, to overlapping layers of septum primum and septum secundum, and (4) the third and fourth loops cooperating with the central body to apply a force, perpendicular to the second plane, to overlapping layers of septum primum and septum secundum.

Claim 1 recites, inter alia, a first and a second planes each substantially parallel to septum primum and septum secundum, and Forber failed to teach or suggest these required limitations. Forber loops extend from the center part to one of the two end caps and are a part of two cones that connect with each other through the center part of the device in an end-to-end fashion. Fig. 8. However, as shown in the left figure below, a plane defined by each of the Forber loops connects both the central body and one of the two caps. At its deployed configuration, the loop forms a substantially triangle shape from the view below. Loop with such substantially triangle shape, thus define a three dimensional structure, not a flat plane as shown in the right figure from the Application, that parallel to either septum primum or septum secundum as required in Applicants invention.



In addition, Forber also failed to teach or suggest the required cooperating loops with the central body to apply forces to overlapping layers of septum primum and septum secundum. claim 1 recites, inter alia, two loops (the first and second loops in one side and the third and fourth loops in the other) each cooperating with the central body to apply a force, perpendicular to the corresponding plane, to overlapping layers of septum primum and septum secundum. Forber did not teach or suggest these limitations.

First, Forber devices do not apply forces to the patent foramen ovale (PFO). Forber states that "[c]onstruction of device 120 begins the same way as in the preferred embodiments 20." Col. 5, lines 55-56. Afterwards, "band assemblies 123 and 127 are pushed toward center band assembly 125 forcing wires 122 to form two disks 130 and 132 as in the preferred embodiment 20." Col. 5, lines 58-60. "The final shape is similar to two cones attached end to end." Claim 1; Abstract; col. 2, lines 11 and 12. As seen in Fig. 6, Forber device has two disks 130 and 132, each disk in the shape of a cone, and the two disks connected through the center band 125 in a peak-to-peak fashion. Fig. 6.

This configuration would not be able to apply a force to overlapping layers of septum primum and septum secundum. In fact, Fig. 8 shows that, although Forber device 120 straddles septal wall 140, because its configuration, it does not apply a force to the septal wall. Fig. 8. It indeed does not need to.

Secondly, Forber teaches away from the claimed inventions. Forber devices occlude by thrombus formation. For example, once a Forber device lodges in a vessel, the device will initiate thrombus formation which will occlude the vessel. Abstract; col. 2, lines 19 and 20. Moreover, in order to increase the efficiency of the thrombus formation, Forber uses large number of wires, for example, 16 to 32 wires. Figs. 6-8; col. 2, lines 23-27; and col. 3, lines 51-53.

However, thrombus formation is one of the very problems that this present application addresses. A PFO creates the possibility for right to left shunt that allows blood clots (thrombosis) to enter the systemic circulation. Application as filed, p. 1, lines 7-12. The claimed inventions are to apply a force to close the PFO in order to reduce the risk of an embolic event. Application as filed, p. 1; lines 20-23. Therefore, Forber teaches away from the present inventions.

Based on the discussion above, Forber failed to teach or suggest at least some of the required limitations in claim 1, for example, (1) the planes defined by the loops and parallel to

septum primum and septum secundum and (2) the loops cooperating with the center part to apply a force to the overlayers of septum primum and septum secundum. Therefore, Forber failed to anticipate claim 1. Further, because claims 4-10, 14, 17-19, and 25-28 depend on claim 1, they are also not anticipated by Forber. Accordingly, Applicants request that the Examiner re-consider and withdraw these rejections.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner rejected claims 11, 13, and 20 under 35 U.S.C. § 103(a) over Forber in view of Huebsch. In addition, the Examiner also rejected claims 12, 21, and 22 on the same ground over Forber in view of Huebsch in view of Neuss. Applicants submit that neither Forber in view of Huebsch nor Forber in view of Huebsch in view of Neuss makes the claimed inventions obvious.

As discussed above, Forber failed to teach at least two required limitations in claim 1, i.e., (1) the planes defined by the loops and parallel to septum primum and septum secundum and (2) the loops cooperating with the center part to apply a forces to the overlayers of septum primum and septum secundum. Huebsch and Neuss, either individually or in combination, did not cure these defects. Specifically, the Examiner states that Huebsch teaches a bioresorbable covered in a material to promote tissue ingrowth. P. 6. The Examiner also states that Huebsch teaches a catheter drawing the device back into the catheter and that Neuss teaches a PFO closure device having loops made of a bioresorbable material. P. 7. However, none of the above teachings addressed Forber's failure in teaching the required planes and/or the required cooperating structure to apply forces to overlapping layers of the PFO. As a result, Forber and Huebsch would not have made obvious what are claimed in claims 11, 13, and 20, and Forber, Huebsch, and Neuss would not have made obvious what are claimed in claims 12, 21, and 22. Accordingly, Applicants request that the Examiner reconsider and withdraw the above rejections.

CONCLUSION

Applicants submit that the claims are now in condition for allowance. Accordingly, a favorable action is thereby respectfully requested. The Examiner is invited to telephone the undersigned to discuss any outstanding issues.

Respectfully submitted,

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